

**FLAWLESS FINISH PERFECTLY NUDE MAKEUP BROAD SPECTRUM SUNSCREEN SPF 15 SHADE VANILLA SHELL- octinoxate and titanium dioxide lotion**

**Elizabeth Arden, Inc**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

-----

**250394**

**DESCRIPTION**

Makeup that feels like your own skin, only better. Light, breathable formula smooths on seamlessly for a naturally luminous look that lasts all day. Minimizes the look of pores and imperfections immediately and over time with continued use. Hydro-pigment color technology, vitamins and antioxidants protect and perfect, so skin looks beautifully even-toned and flawless.

**INDICATIONS & USAGE**

smooth onto face.

**WARNINGS**

**For external use only**

**OTC - ACTIVE INGREDIENT**

OCTINOXATE 4.00%.....Sunscreen

TITANIUM DIOXIDE 1.26%....Sunscreen

**INACTIVE INGREDIENT**

WATER/AQUA/EAU, ISOHEXADECANE, HEXYL LAURATE, MICA, GLYCERIN, POLYGLYCERYL-4 ISOSTEARATE, POTASSIUM CETYL PHOSPHATE, CETEARYL ALCOHOL, ASCORBYL PALMITATE, BETAINE, CARBOMER, GLYCERYL STEARATE, HYDROLYZED VEGETABLE PROTEIN, LECITHIN, MAGNESIUM ALUMINUM SILICATE, PEG-100 STEARATE, POLYGLYCERYL-10 MYRISTATE, SODIUM HYDROXIDE, TOCOPHERYL ACETATE, TREMELLA FUCIFORMIS SPOROCARP EXTRACT, CHLORPHENESIN, PHENOXYETHANOL, POTASSIUM SORBATE, SODIUM BENZOATE, SODIUM DEHYDROACETATE [MAY CONTAIN/PEUT CONTENIR (+/-) IRON OXIDES (CI 77491, CI 77492, CI 77499), TITANIUM DIOXIDE (CI 77891).

**OTC - DO NOT USE**

**Do not**

use on damaged or broken skin

**OTC - KEEP OUT OF REACH OF CHILDREN**

**Keep out of reach of children.**

**OTC - PURPOSE**

Provides SPF 15 sun protection.

**OTC - STOP USE**

**Stop use and ask a doctor if rash occurs**

**OTC - WHEN USING**

keep out of eyes. Rinse with water to remove.

**Drug Facts (continued)**

- For all skin types.
- Light to medium coverage. Natural radiant finish.
- Makeup that feels like your own skin, only better. Light, breathable formula smooths on seamlessly for a naturally luminous look that lasts all day.
- Minimizes the look of pores and imperfections immediately and over time with continued use.
- Hydro-pigment color technology, vitamins and antioxidants protect and perfect, so skin looks beautifully even-toned and flawless.
- To use: smooth onto face.
- Clinically, dermatologist and allergy tested.

**Drug Facts**

Active Ingredients	Purpose
OCTINOXATE 4.00%	Sunscreen
TITANIUM DIOXIDE 1.26%	Sunscreen

**Uses**

- Helps prevent sunburn
- If used as directed with other sun protection measures (see **Directions**), decreases the risk of skin cancer and early skin aging caused by the sun

**Warnings**

- For external use only
- Do not use on damaged or broken skin
- When using this product keep out of eyes. Rinse with water to remove.

**Directions For Sunscreen Use:**

- Apply liberally 15 minutes before sun exposure
- Reapply:
  - at least every 2 hours
- Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a broad spectrum SPF of 15 or higher and other sun protection measures including:
  - Limit time in the sun, especially from 10 a.m. – 2 p.m.
  - Wear long-sleeve shirts, pants, hats, and sunglasses
  - Children under 6 months: Ask a doctor.

**Inactive Ingredients**  
 WATER/AQUA/EAU, ISOHEXADECANE, HEXYL LAURATE, MICA, GLYCERIN, POLYGLYCERYL-4

**Drug Facts (continued)**

ISOSTEARATE, POTASSIUM CETYL PHOSPHATE, CETEARYL ALCOHOL, ASCORBYL PALMITATE, BETAINE, CARBOMER, GLYCERYL STEARATE, HYDROLYZED VEGETABLE PROTEIN, LECITHIN, MAGNESIUM ALUMINIUM SILICATE, PEG-100 STEARATE, POLYGLYCERYL-10 MYRISTATE, SODIUM HYDROXIDE, TOCOPHERYL ACETATE, TREMELLA FUCIFORMIS SPOROCARP EXTRACT, CHLORPHENESIN, PHENOXYETHANOL, POTASSIUM SORBATE, SODIUM BENZOATE, SODIUM DEHYDROACETATE [MAY CONTAIN/PEUT CONTENIR (+/-) IRON OXIDES (CI 77491, CI 77492, CI 77499), TITANIUM DIOXIDE (CI 77891).

**Other Information**

- Protect this product from excessive heat and direct sun

**Questions or comments?**

- Call toll free 1-800 326-7337

**Flawless Finish Perfectly Nude Makeup Broad Spectrum Sunscreen SPF 15**

1 FL. OZ. 30 ml

**FLAWLESS FINISH PERFECTLY NUDE MAKEUP BROAD SPECTRUM SUNSCREEN SPF 15 SHADE VANILLA SHELL**

octinoxate and titanium dioxide lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67938-2007
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	

<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	60 mg in 1500 mg
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	18.9 mg in 1500 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>ISOHEXADECANE</b> (UNII: 918X10UF1E)	
<b>HEXYL LAURATE</b> (UNII: 4CG9F9W01Q)	
<b>MICA</b> (UNII: V8A1AW0880)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>POLYGLYCERYL-4 ISOSTEARATE</b> (UNII: 820DPX33S7)	
<b>POTASSIUM CETYL PHOSPHATE</b> (UNII: 03KCY6P7UT)	
<b>ASCORBYL PALMITATE</b> (UNII: QN83US2B0N)	
<b>BETAINE</b> (UNII: 3SCV180C9W)	
<b>MAGNESIUM ALUMINUM SILICATE</b> (UNII: 6M3P64V0NC)	
<b>PEG-100 STEARATE</b> (UNII: YD01N1999R)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>CHLORPHENESIN</b> (UNII: I670DAL4SZ)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SODIUM DEHYDROACETATE</b> (UNII: 8W46YN971G)	

### Product Characteristics

<b>Color</b>	BROWN (LIGHT BEIGE)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67938-2007-1	1 in 1 BOX		
1	NDC:67938-2007-2	1500 mg in 1 BOTTLE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	07/17/2013	

**Labeler** - Elizabeth Arden, Inc (849222187)

### Establishment

Name	Address	ID/FEI	Business Operations
Intercos		883457061	manufacture(67938-2007)

